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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,626	12/01/2000	Elisabeth A. Raleigh	NEB-165-PUS	8938

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EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/701,626	Applicant(s) Raleigh
	Examiner Arun Chakrabarti	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 22, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14 and 17-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *7-14 and 17* is/are allowed.

6) ☒ Claim(s) *1-6 and 18-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Current Status of the Application

1. Applicant's amendment submitted on December 22, 2003, has been entered. Claim 1 has been amended. Claims 1-14 and 17-20 are currently pending in this application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Aslanidis et al. (Proceedings of the National Academy of Sciences (USA), (August 1991), Vol. 88, pp. 6765-6769) in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995).

Aslanidis et al teaches a method for cloning of one or more genes in a cassette array (Abstract), the array being characterized by a plurality of genes where each gene is embedded in a predictable nucleotide sequence context including a repeat DNA sequence, the method comprising the steps of:

a) hybridizing oligonucleotide primers to identified repeat sequences in the cassette array (Abstract and MATERIALS AND METHODS Section, Amplification of Human DNA Subsection and Figure 1);

b) amplifying the DNA between the hybridized primers of step (a) to produce DNA fragments which inherently contain one or more genes (Abstract and MATERIALS AND METHODS Section, Amplification of Human DNA Subsection and RESULTS Section and Figure 1). This inherency is borne out of the fact that human chromosomes, especially 19q13.2 region studied by Aslanidis et al, comprises at least one gene (Gene NO: 13, as disclosed by Ruben et al. (U.S. Patent 6,420,526 B1) (July 16, 2002)) ;

c) ligating the DNA fragments of step (b) into a vector for cloning the one or more genes in a host cell (MATERIALS AND METHODS Section, Heteroduplex Formation of PCR fragments Subsection and Figure 1);

Aslanidis et al teaches a method, wherein the oligonucleotides contain recognition sites which permit directional cloning (RESULTS Section, Design of cloning procedure Subsection).

Aslanidis et al inherently teaches a method, wherein the DNA fragments are ligated into the vector in an orientation that enables expression (MATERIALS AND METHODS Section, Heteroduplex Formation of PCR fragments Subsection).

Aslanidis et al does not teach a method for cloning one or more prokaryotic genes.

Fiers et al. teaches a method for cloning one or more prokaryotic genes (Abstract and Column 20, line 17 to Column 24, line 54).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method for cloning one or more prokaryotic genes of Fiers et al. in the method of Aslanidis et al. since Fiers et al. states, "Improved vectors and methods for expressing cloned genes of prokaryotic or eukaryotic origin and methods of making such vectors are disclosed, the improved vectors comprising promoters and operators from lambda phages and preferably do not include an active cro gene or an active N gene, the vectors having at least one endonuclease recognition site for cloning desired genes less than about 300 base pairs from the promoters and operators and being useful, as are methods utilizing the vectors, in producing a wide variety of prokaryotic, eukaryotic and vital polypeptides, hormones, enzymes, antigens, proteins and amino acids (Abstract)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus

permitting greater flexibility in the selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method for cloning one or more prokaryotic genes of Fiers et al. in the method of Aslanidis et al. in order to achieve the express advantages, as noted by Fiers et al., of a cloning technique which provides improved vectors comprising promoters and operators from lambda phages and preferably do not include an active cro gene or an active N gene, the vectors having at least one endonuclease recognition site for cloning desired genes less than about 300 base pairs from the promoters and operators and being useful, as are methods utilizing the vectors, in producing a wide variety of prokaryotic, eukaryotic and vital polypeptides, hormones, enzymes, antigens, proteins and amino acids.

4. Claims 2 and 18 are rejected under 35 U.S.C. 103 (a) over Russell et al. (U.S. Patent 6,312,944 B1) (November 6, 2001) in view of Aslanidis et al. (Proceedings of the National Academy of Sciences (USA), (August 1991), Vol. 88, pp. 6765-6769) further in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995)..

Russell et al. teaches a method of cloning the diversity-selected genes comprising adhesin peptides fimbrial protein genes (Abstract and Example, and Example 2).

Russell et al. does not teach a method for cloning according to claim 1.

Aslanidis et al. in view of Fiers et al. teach a method for cloning according to claims 1 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art

at the time the invention was made to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising adhesin peptides fimbrial protein genes of Russell et al. since Aslanidis et al. state, "Coincidence cloning allows the isolation of sequences held in common by two genomic DNA populations (Abstract, first sentence)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus permitting greater flexibility in the selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising adhesin peptides fimbrial protein genes of Russell et al. in order to achieve the express advantages, as noted by Aslanidis et al., of a cloning technique which allows the isolation of sequences held in common by two genomic DNA populations and which permits greater flexibility in the selection of regions for probe isolation.

5. Claim 3 is rejected under 35 U.S.C. 103 (a) over Xu (U.S. Patent 5,492,823) (February 20, 1996) in view of Aslanidis et al. (Proceedings of the National Academy of Sciences (USA), (August 1991), Vol. 88, pp. 6765-6769) further in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995).

Xu teaches a method of cloning the diversity-selected genes comprising restriction-endonuclease genes (Abstract and Examples 1-5 and Figure 3).

Xu does not teach a method for cloning according to claim 1.

Aslanidis et al. in view of Fiers et al. teach a method for cloning according to claims 1 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising restriction-endonuclease genes of Xu since Aslanidis et al. states, "Coincidence cloning allows the isolation of sequences held in common by two genomic DNA populations (Abstract, first sentence)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus permitting greater flexibility in the selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising restriction-endonuclease genes of Xu in order to achieve the express advantages, as noted by Aslanidis et al., of a cloning technique which allows the isolation of sequences held in common by two genomic DNA populations and which permits greater flexibility in the selection of regions for probe isolation.

6. Claim 4 is rejected under 35 U.S.C. 103 (a) over Stein et al. (U.S. Patent 5,491,060) (February 13, 1996) in view of Aslanidis et al. (Proceedings of the National Academy of Sciences

(USA), (August 1991), Vol. 88, pp. 6765-6769) further in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995).

Stein et al. teaches a method of cloning the diversity-selected genes comprising methyltransferase genes (Abstract and Column 2, lines 15-44 and Example).

Stein et al. does not teach a method for cloning according to claim 1.

Aslanidis et al. in view of Fiers et al. teach a method for cloning according to claims 1 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising methyltransferase genes of Stein et al. since Aslanidis et al. states, "Coincidence cloning allows the isolation of sequences held in common by two genomic DNA populations (Abstract, first sentence)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus permitting greater flexibility in the selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of cloning of Aslanidis et al. in view of Fiers et al. in the method of cloning the diversity-selected genes comprising methyltransferase genes of Stein et al. in order to achieve the express advantages, as noted by Aslanidis et al., of a cloning technique which allows the isolation of sequences held in common by

two genomic DNA populations and which permits greater flexibility in the selection of regions for probe isolation.

7. Claim 19 is rejected under 35 U.S.C. 103 (a) over Gruber et al. (U.S. Patent 6,495,349 B1) (December 17, 2002) in view of Russell et al. (U.S. Patent 6,312,944 B1) (November 6, 2001) further in view of Aslanidis et al. (Proceedings of the National Academy of Sciences (USA), (August 1991), Vol. 88, pp. 6765-6769) further in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995).

Gruber et al. teaches a method of cloning the diversity-selected genes comprising signaling peptide kinases genes (Example 4).

Gruber et al. does not teach a method for cloning according to claims 1-2.

Russell et al in view of Aslanidis et al. in view of Fiers et al. teach a method for cloning according to claims 1-2 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of Russell et al in view of Aslanidis et al further in view of Fiers et al. in the method of cloning the diversity-selected genes comprising signaling peptide kinases genes of Gruber et al. since Aslanidis et al. state, "Coincidence cloning allows the isolation of sequences held in common by two genomic DNA populations (Abstract, first sentence)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus permitting greater flexibility in the

selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of Russell et al in view of Aslanidis et al. further in view of Fiers et al. in the method of cloning the diversity-selected genes comprising signaling peptide kinases genes of Gruber et al. in order to achieve the express advantages, as noted by Aslanidis et al., of a cloning technique which allows the isolation of sequences held in common by two genomic DNA populations and which permits greater flexibility in the selection of regions for probe isolation.

8. Claim 20 is rejected under 35 U.S.C. 103 (a) over Coruzzi et al. (U.S. Patent 5,391,725) (February 21, 1995) in view of Russell et al. (U.S. Patent 6,312,944 B1) (November 6, 2001) further in view of Aslanidis et al. (Proceedings of the National Academy of Sciences (USA), (August 1991), Vol. 88, pp. 6765-6769) further in view of Fiers et al. (U.S. Patent 5,401,658) (March 28, 1995).

Coruzzi et al. teaches a method of cloning the diversity-selected genes comprising detoxifying enzymes (drug resistant determinant) genes (Column 14, lines 37-51).

Coruzzi et al. does not teach a method for cloning according to claims 1-2.

Russell et al in view of Aslanidis et al. further in view of Fiers et al. teach a method for cloning according to claims 1-2 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of Russell et al in view of Aslanidis et al. further in view of Fiers et al. in the method of cloning the diversity-selected

genes comprising detoxifying enzymes (drug resistant determinant) genes of Coruzzi et al. since Aslanidis et al. state, "Coincidence cloning allows the isolation of sequences held in common by two genomic DNA populations (Abstract, first sentence)". Aslanidis et al further provides motivation as Aslanidis et al states, "This approach allows the boundaries for the regional probe isolation to be defined by combinations of hybrids rather than single cell lines, thus permitting greater flexibility in the selection of regions for probe isolation (Abstract, last sentence)". By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of Russell et al in view of Aslanidis et al. further in view of Fiers et al. in the method of cloning the diversity-selected genes comprising detoxifying enzymes (drug resistant determinant) genes of Coruzzi et al. in order to achieve the express advantages, as noted by Aslanidis et al., of a cloning technique which allows the isolation of sequences held in common by two genomic DNA populations and which permits greater flexibility in the selection of regions for probe isolation.

Allowable Subject Matter

9. Claims 7-14, and 17 are allowed because no prior art of record either teaches or suggests the SEQ ID Numbers disclosed in the claims.

Response to Amendment

10. In response to amendment, previous 102(b) rejection has been withdrawn. However, new 103(a) rejections have been included.

Response to Arguments

11. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (571) 272-0740. If attempts to reach the examiners by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (571) 272-0518. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 872-9306. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti
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January 20, 2004

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